VZCZCXYZ0000
RR RUEHWEB

DE RUEHBU #0406/01 0482043
ZNR UUUUU ZZH
R 172043Z FEB 06
FM AMEMBASSY BUENOS AIRES
TO RUEHC/SECSTATE WASHDC 3529
INFO RUEHAC/AMEMBASSY ASUNCION 5344
RUEHBR/AMEMBASSY BRASILIA 5128
RUEHLP/AMEMBASSY LA PAZ FEB MONTEVIDEO 5320
RUEHSG/AMEMBASSY SANTIAGO 4944
RUEHRI/AMCONSUL RIO DE JANEIRO 1875
RUEHSO/AMCONSUL SAO PAULO 2769

UNCLAS BUENOS AIRES 000406

SIPDIS

SIPDIS

DEPT FOR EB/IPE CLACROSSE AND ANNA MARIA ADAMO
DEPT PLS PASS TO USTR JCHOE-GROVES
DOC FOR JBOGER, PLEASE PASS TO USPTO JURBAN AND LOC STEPP

E.O. 12958: N/A
TAGS: KIPR ETRD ECON AR
SUBJECT: ARGENTINA'S 2006 SPECIAL 301 REVIEW

REF: A. STATE 014937

¶B. 05 BUENOS AIRES 01566
¶C. 05 BUENOS AIRES 01047

Summary

¶1. Argentine entities responsible for upholding IPR failed to translate the momentum from a strong 2004 into tangible successes in 2005. U.S. pharmaceutical companies are still waiting for commercially valuable patents; CD and DVD piracy rates appear to be rising, despite Argentina's economic recovery; and a piece of draft legislation that would have bolstered the protection of trademarked goods died in committee during the year. The Embassy therefore recommends that Argentina remain on the Special 301 Priority Watch List until it can begin to point to concrete results across the IPR gamut and, more specifically, until it ensures effective protection of confidential and proprietary data developed by pharmaceutical companies. End Summary.

Patents

¶2. Argentina's patent and trademark agency, The National Institute of Industrial Property (INPI), made significant progress toward streamlining Argentina's patent system over the past several years. That system appeared close to breakdown until 2002, with patent applications coming in much more quickly than they could be processed. From 1995 until 2002, for example, the INPI received 47,573 patent applications but was able to resolve only 28,190 of those in the queue, for a deficit of over 19,000 applications in those eight years alone. That situation has now turned around, with the INPI receiving 14,106 patent applications during 2003-2005 and resolving 18,334 during the same period. Additionally, the rate at which the number of applications resolved exceeds the number of applications received is increasing.

¶3. INPI's improved efficiency stems from a number of reforms that began to be introduced in 2003. The INPI, via a series of resolutions, implemented fast-track procedures to reduce what had grown to be a large patent application backlog of over 30,000 cases. Specifically, all persons or companies having more than one patent application pending were given

the opportunity to rank-order their applications, allowing them to jump the application of a potentially more-valuable product ahead of a less-promising application that had been submitted at an earlier date. U.S. and other research-based pharmaceutical companies are also now authorized to present studies used in other patent-granting countries to support patent requests in Argentina, significantly easing the INPI's investigation requirements.

¶4. The GOA also increased the INPI's budget by 11 percent in 2004, and kept those gains during 2005. The extra money allowed the hiring of 27 new patent examiners, 10 of them in the key pharmaceutical area. That initiative doubled the total number of pharmaceutical examiners to 20. The INPI has instituted a system of in-house training that an INPI executive told Econoff has increased the examiners' efficiency by up to 30 percent. One result has been a reduction in the time it takes a patent application to receive a preliminary examination from fifteen months to eleven months. In another positive development, the INPI sent two of its pharmaceutical inspectors to the U.S. Patent and Trademark Office's (USPTO) academy for training in 2005. That training, arranged by the Embassy and jointly funded by the USPTO and research-based pharmaceutical companies, was a first for Argentine patent inspectors. The Embassy also arranged for an Argentine appeals court judge specializing in IPR cases to attend USPTO training, another first.

¶5. The gains mentioned above, while undeniably positive, proceed from a very low baseline. The right to patent pharmaceutical products in Argentina was recognized only in 1996, and the first pharmaceutical patents were issued following the expiration of the TRIPS transition period in October 2000. Even those patents were for approximately 80 products of marginal commercial value. A small number of other pharmaceutical patents of greater value were granted in subsequent years, but only after long and arduous processes. Many of the patent applications the INPI counted as "resolved" during 2005 were simply discarded after the applicant failed to respond to an INPI instruction to formally reaffirm the application.

¶6. The lack of patents for many products, coupled with Argentina's devaluation in 2002, which resulted in sharp price increases for imported products, increased incentives for local pharmaceutical companies to produce unlicensed copies of products that had been patented or for which patents were pending. The combination of these factors has had a negative effect on the Argentina-derived business of U.S.-based pharmaceutical companies. According to CAEMe, the Argentine association that represents U.S. and other research-based pharmaceutical companies, local pharmaceutical firms now have over 50 percent of the Argentine market and have reached almost 50 percent of the export market.

¶7. Argentina amended its patent law (Law 24,481) in December 2003 to implement an agreement between the USG and the GOA that had been signed in May 2002. That agreement came after approximately three years of consultations under the WTO's dispute settlement mechanism. In a related development, the U.S. agreed to give consideration to an Argentine request to add specific products to the U.S. Generalized System of Preferences (GSP) that allows for duty-free entry into the U.S. The remaining unresolved pharmaceutical patent issue relates to the effective legal protection of confidential and proprietary data developed by pharmaceutical companies to demonstrate the efficacy and safety of new medicines. U.S. and other research-based pharmaceutical companies believe this to be a critical issue and Argentina and the U.S. have agreed to leave this issue within the WTO dispute settlement mechanism for future action. (Note: The absence of data protection has lead research-based pharmaceutical companies to complain that Argentine health regulatory authorities (ANMAT) rely inappropriately on data supplied by research-based companies to approve unauthorized copies of innovative medicines. According to CAEMe, ANMAT interprets the public disclosure of partial data as an indicator that the data should be regarded as in the public domain.)

¶8. U.S. pharmaceutical companies also remain concerned about the legal implications of two specific clauses in the 2003 agreement. Specifically, the amendment mandates an expert opinion that can challenge the validity of a patent, and requires consideration of the economic impact of an injunction on both parties before the seizure of goods alleged to violate the patent law. Since the agreement was signed, research-based pharmaceutical companies have feared that those clauses could preclude the granting of preliminary injunctive relief and limit the success they have achieved in protecting their products through the use of preliminary injunctions.

¶9. 2005 was the first year during which those fears were realized. A U.S.-based pharmaceutical company discovered several competitors trying to sell copies of its most profitable drug, and sought injunctions to prevent those sales. In one case, the issuance of an injunction was delayed for months, and in another the application for an injunction was rejected by a judge swayed by a local expert hired by the defense, who claimed that the copycat drug did not violate the U.S. pharmaceutical company's patent. In another instance, a different U.S.-based pharmaceutical company went to court to remove five copies of one of its joint-venture drugs from the Argentine market. In a promising ruling, the judge issued injunctions ordering the copies off the market (Reftel B). More than six months after the decision, however, those injunctions have yet to be enforced.

¶10. A frequent complaint of U.S. pharmaceutical companies is that there remains in Argentina no regulatory linkage between the INPI and the ANMAT. While such linkage is not required by TRIPS, its absence in Argentina allows ANMAT to grant local pharmaceutical producers authorization to manufacture and sell products that have already been patented or for which a patent has been requested. The Embassy and multinational pharmaceutical companies have urged the GOA to establish a linkage between ANMAT and INPI that would prevent ANMAT from continuing to authorize local pharmaceuticals to produce products for which an INPI patent has been granted or is pending. There were hints during 2005 of the beginnings of a cooperative relationship between INPI and ANMAT (Reftel C), but the Embassy has no evidence that such cooperation has developed. As things stand, U.S. and other research-based pharmaceutical companies must incur the legal costs of obtaining injunctions to stop the production and sale of products produced by local pharmaceutical companies for which the research-based companies have INPI patents.

¶11. Law 25,649 adopted in 2002 requires medical doctors to use a drug's generic name in all prescriptions. It is believed that this law diverts sales from innovative medicines to TRIPS-infringing copy products. U.S. and other research-based pharmaceutical companies say that true generics do not exist in Argentina because copy products are not required to demonstrate their bioequivalence or bioavailability with original products, meaning local producers can sell drug copies that lack quality and safety assurances. According to Law 25,649, doctors may also include a trademarked version of a drug in their prescriptions, but pharmacists may still offer a substitute. According to Law 25,649, reasons must be indicated on a prescription if a medical doctor does not want the prescription substituted by a pharmacist. Another area of concern is that Argentina has yet to become a contracting state to the World Intellectual Property Organization's (WIPO) Patent Cooperation Treaty.

Copyrights

¶12. Optical Media Piracy: The incidence of CD and DVD piracy in Argentina does not appear to have declined in 2005. Problems in this area include the widespread and open sale of pirated copies of albums and videos and an apparently

increasing number of businesses that offer home delivery of pirated artistic content. Argentina's laws provide generally good nominal protection. However, the lack of any real bite (pirates have not faced jail time), coupled with the extra incentive provided by Argentina's devaluation in 2002, which spiked prices for imported media, has spurred piracy. A local attorney working copyright issues told Econoff that his clients estimate that losses to U.S. companies due to optical media piracy in Argentina exceeded USD 150 million in 2004. The same attorney said that while the Argentine legal system does not function at a first-world level, it is "not bad for the region." The legal system will generally respond when needed to effect the seizure of counterfeit media, the attorney said, but the existence of a personal relationship with relevant authorities is helpful. Still, his client (a IP content trade association) worked with police to effect over 200 raids and seize over 100,000 pirated discs during ¶2005.

¶13. Use/Procurement of Government Software: The GOA has yet to fully comply with its 1999 agreement with the local software industry to legalize unlicensed software used in offices of the national government, and many GOA offices continue to use pirated software. Ministry of Interior Director of Information Management Eduardo Thill told a local news outlet in January 2005 that 90 percent of GOA agencies employing licensed software are using it illegally. There is a GOA move toward open source software, according to Thill, but there has been no legislation to date to bind the GOA to open source software solutions. That situation held true throughout 2005, although a representative of Thill's office told the Embassy February 2006 that the percentage of GOA agencies using licensed software illegally had fallen to between 80 and 85 percent.

¶14. Amendments to Existing Legislation: A promising piece of legislation to modernize Argentina's quarter-century old trademark law (Law 22,362) died in committee in 2005. That draft law, introduced in August 2004, contained several measures that would have strengthened Argentina's anti-trademark piracy regime. Specifically, the draft law would have: involved Argentina's tax agency (AFIP) in trademark piracy (counterfeit merchandise) investigations; expanded the authority of Argentina's Financial Investigations Unit (UIF) to include trademark piracy among the crimes that entity is able to investigate; and increased penalties for those convicted of trademark piracy (eliminating community service as a possible sentence). The Embassy was told by a local attorney who helped to draft the legislation that it will be re-introduced in April 2006. The same attorney blames the failure of the bill on the lethargy of local Argentine business chambers, which he said did not actively support the effort.

Trademarks

¶15. Argentina's trademark law (Law 22,362) fulfills international standards, but legislation subsequent to its enactment has rendered it relatively ineffective, with penalties limited to probation and fines that are not high enough to act as a significant deterrent (see paragraph 14). The process of renewing trademarks is an area where INPI's increasing efficiency has become evident. Whereas an applicant for renewal had to wait five months only a few years ago, the process is now completed in less than two months. Raids by local police on flea markets where counterfeit merchandise is openly sold have not been frequent or widespread enough to lessen the availability of pirated goods. Representatives of industries frequently targeted by counterfeiters claim that over forty large, well-established markets exist in Buenos Aires alone that are almost completely dedicated to the sale of counterfeit goods (in addition to innumerable smaller points of sale throughout the country).

Plant Variety

¶16. Argentine farmers have the right to replant -- although not to sell -- seed generated from a harvest originating from registered seeds without paying royalties. However, Argentine farmers continue to sell "brown bag" seed (as opposed to bags of seed showing brand names) as brand-name product. This is a widespread problem with soybean seed, and it underlies Monsanto's recent court actions in Europe, which have resulted in ships carrying Argentine soy being stopped and the cargo seized. Monsanto's actions are aimed at collecting royalties that Argentine farmers are not paying via legal challenges in countries in which Monsanto has patent protection for the Roundup Ready soybean technology. Farm associations and industry representatives generally agree that Argentina must elaborate and enact a new seed law that better protects intellectual property, but negotiations toward that end have broken down as of this writing. The sale of "brown-bag" seed from Argentina to neighboring countries has also led to the significant production of unregistered biotech soybeans in Brazil and Paraguay. Argentina is a party to the 1978 Act of the International Union for the Protection of New Varieties of Plants (UPOV), but has not signed the 1991 UPOV convention.

Training

¶17. Reluctance by the various enforcement entities to cooperate with each other is a problem that has long contributed to ineffective anti-piracy action in Argentina. The Embassy would therefore encourage any IPR training that emphasizes a team approach and brings together representatives from the full range of GOA institutions involved in anti-piracy efforts. The trust and familiarity that would result from such officials being brought together, even if only for a short training session, would help to foster inter-agency teamwork of the sort necessary to effectively combat piracy.

Comment and Recommendation

¶18. The Embassy's Special 301 report for 2005 said: "Most of the persons interviewed for this report believe that 2005 will be the year when it becomes clear whether the legal and administrative improvements of the recent past will finally manifest themselves in tangible successes." There was evidence of improvement during 2005, but very few of the hoped-for tangible successes. INPI appears to be functioning more efficiently, but that procedural improvement has not translated into the issuance of patents with significant commercial value for U.S. pharmaceutical companies. Piracy has not diminished, despite a significant recovery from an economic crisis that was a real spur to piracy. Neither has Argentina's legislature taken the steps necessary to clamp down on piracy. As also noted herein, the Argentine legal system remains an uncertain ally in the fight to protect intellectual property. The Embassy therefore recommends that Argentina remain on the Special 301 Priority Watch List for ¶2006. End Comment.

¶19. To see more Buenos Aires reporting, visit our classified website at: http//www.state.sgov.gov/p/wh/buenosaires
GUTIERREZ